K071046

OCT 23 2007

510(k) Summary

Submitter:

Synthes Biomaterials
1230 Wilson Drive
West Chester, PA 19380

Company Contact:

Jeffrey L. Dow, JD
Director, Clinical & Regulatory Affairs
Synthes Biomaterials
484 356 9720
dow.jeff@synthes.com

Name of Device:

Synthes chronOS Composite

Device Classification:

Class II, 21 CFR § 888.3045

Product Code:

MQV

Common Name:

Resorbable Calcium Salt Bone Void Filler

Predicate Devices:

Synthes (USA) chronOS™ (K043045)
chronOS TCP (K013072)

Intended Use:

Synthes chronOS Composite is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Synthes chronOS Composite is indicated for use in the treatment of bony defects created surgically or through traumatic injury.

Synthes chronOS Composite, combined with autogenous blood and/or bone marrow or autograft, is intended to be used in spine for posterolateral fusion. Following placement into the bony void, chronOS Composite resorbs and is replaced with bone during the healing process.

Device Description:

Synthes chronOS Composite is a synthetic, porous, osteoconductive, resorbable bone void filler made from chronOS ß-TCP granules imbedded in a matrix of poly (lactide-co-ε-caprolactone). The composite is flexible and may be molded by the surgeon or used directly as supplied. The flexible chronOS Composite provides contourability and malleability of the device to the bony implant site.

Substantial Equivalency: Documentation is provided which demonstrates that Synthes chronOS Composite is substantially equivalent[1] to other legally marketed Synthes devices.

[1] The term "substantial equivalence" as used in the 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended, and as applied under 21 CFR Part 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US patent laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2007

Synthes Biomaterials
% Jeffrey L. Dow, JD
1230 Wilson Drive
West Chester, PA 19380

Re: K071046
Trade/Device Name: Synthes chronOS™ β-TCP Composite
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: October 18, 2007
Received: October 22, 2007

Dear Mr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K071046

Device Name: Synthes chronOS™ Composite

Indications: Synthes chronOS Composite is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Synthes chronOS Composite is indicated for use in the treatment of bony defects created surgically or through traumatic injury.

Synthes chronOS Composite , combined with autogenous blood and/or bone marrow or autograft, is intended to be used in spine for posterolateral fusion. Following placement into the bony void, chronOS Composite resorbs and is replaced with bone during the healing process.

Prescription Use __ X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071046